DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL 24 1998

Re: Posicor
Docket No.: 97E-0462

#16

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, DC 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,808,605, filed by Hoffman-La Roche,Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Posicor, the human drug product claimed by the patent.

The total length of the regulatory review period for Posicor is 1,793 days. Of this time, 1,326 days occurred during the testing phase and 467 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: July 25, 1992.

   The applicant claims July 24, 1992, as the date the Investigational New Drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 25, 1992, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: March 11, 1996.

   The applicant claims March 8, 1996, as the date the New Drug Application (NDA) for Posicor (NDA 20-689) was initially submitted. However, FDA records indicate that NDA 20-689 was submitted on March 11, 1996.

3. The date the application was approved: June 20, 1997.

   FDA has verified the applicant's claim that NDA 20-689 was approved on June 20, 1997.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Thomas J. McGinnis

Thomas J. McGinnis, R.Ph.
Deputy Associate Commissioner
for Health Affairs

cc: George W. Johnstone
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